

**NON-BLOOD
BIOLOGICAL PRODUCT DEVIATION CODES
FY02**

IM--** INCOMING MATERIAL SPECIFICATIONS**

IM-10- Miscellaneous**

IM-10-01 Other

IM-12- Container**

IM-12-01 Specifications not met

IM-12-02 Defective

IM-13- Closures**

IM-13-01 Specifications not met

IM-13-02 Defective

IM-14- Source or raw material does not meet specifications or otherwise found to be unsuitable**

IM-14-01 Other

IM-14-02 Contains precipitate

IM-14-03 Contaminated with microorganism

IM-14-04 Contaminated with mold

IM-14-05 Impurities exceed specification

IM-14-06 Testing deviation

IM-14-07 Stored or shipped at incorrect temperature or lack of controlled temperature

PC--** PROCESS CONTROLS**

PC-20- Miscellaneous**

PC-20-01 Other

PC-21- Manufacturing or processing performed using incorrect parameters**

PC-21-01 Other

PC-21-02 Incorrect temperature

PC-21-03 Filling not performed according to specifications

PC-21-04 Aseptic processing procedures not performed according to specifications

PC-22- Process/Procedure**

PC-22-01 Other

PC-22-02 Interruption of process

PC-22-03 Environmental monitoring excursions

PC-22-04 Equipment not qualified

PC-22-05 Sanitization not performed or performed incorrectly

PC-22-06 Failed media fill

PC-23- Process Water - specification not met**

PC-23-01 Other

PC-23-02 Water for injection

PC-23-03 Purified water

PC-24- Bulk material does not meet specifications or otherwise found to be unsuitable**

PC-24-01 Other

PC-24-02 Contains precipitate
PC-24-03 Contaminated with microorganism
PC-24-04 Contaminated with mold
PC-24-05 Impurities exceed specification
PC-24-06 Stored at incorrect temperature
PC-24-07 Stored for an excessive hold time

TE-**-** TESTING

TE-30-** Miscellaneous

TE-30-01 Other

TE-31-** Safety

TE-31-01 Performed incorrectly

TE-31-02 Not performed or not documented

TE-32-** Purity

TE-32-01 Performed incorrectly

TE-32-02 Not performed or not documented

TE-33-** Potency

TE-33-01 Performed incorrectly

TE-33-02 Not performed or not documented

TE-34-** Sterility

TE-34-01 Performed incorrectly

TE-34-02 Not performed or not documented

TE-35-** Identity

TE-35-01 Performed incorrectly

TE-35-02 Not performed or not documented

TE-36-** Stability

TE-36-01 Performed incorrectly

TE-36-02 Not performed or not documented

LA-**-** LABELING

LA-40-** Miscellaneous

LA-40-01 Other

LA-41-** Package insert

LA-41-01 Incorrect

LA-41-02 Missing

LA-41-03 Not current or approved

LA-42-** Product label

LA-42-01 Incorrect

LA-42-02 Missing

LA-43-** Carton label

LA-43-01 Incorrect

LA-43-02 Missing

LA-44-** Expiration date

LA-44-01 Extended

LA-44-02 Missing

LA-45-** Lot number

- LA-45-01 Incorrect
- LA-45-02 Missing
- LA-46-** Storage temperature
 - LA-46-01 Incorrect
 - LA-46-02 Missing
- LA-47-** Administration route
 - LA-47-01 Incorrect
 - LA-47-02 Missing
- LA-48-** Concentration or volume
 - LA-48-01 Incorrect
 - LA-48-02 Missing

PS-**-** PRODUCT SPECIFICATIONS

- PS-50-** Miscellaneous
 - PS-50-01 Other
- PS-51-** Product specification not met
 - PS-51-01 Other
 - PS-51-02 Contains precipitate
 - PS-51-03 Contaminated with microorganism
 - PS-51-04 Contaminated with mold
 - PS-51-05 Impurity levels
 - PS-51-06 Moisture
 - PS-51-07 Preservative content
 - PS-51-08 Potency
 - PS-51-09 Appearance
 - PS-51-10 Fill volume
- PS-52-** Component packaged with final product did not meet specifications
 - PS-52-01 Other
 - PS-52-02 Contains precipitate
 - PS-52-03 Contaminated with microorganism
 - PS-52-04 Contaminated with mold
 - PS-52-05 Fill volume
- PS-53-** Stability testing failed
 - PS-53-01 Other
 - PS-53-02 Potency
 - PS-53-03 Preservative
 - PS-53-04 Container closure integrity
 - PS-53-05 Chemical analysis/purity
- PS-54-** Administration set (packaged with product) incorrect or incomplete
 - PS-54-01 Other
 - PS-54-02 Incorrect or missing label
 - PS-54-03 Defective
 - PS-54-04 Expired

QC-**-** QUALITY CONTROL AND DISTRIBUTION

- QC-60-** Miscellaneous

- QC-60-01 Other
- QC-61-** Product distributed inappropriately
 - QC-61-01 Other
 - QC-61-02 Product distributed prior to completion of required testing
 - QC-61-03 Product distributed prior to CBER approval of a PAS
 - QC-61-04 Product distributed less than 30 days after submission of CBE-30
 - QC-61-05 Product distributed prior to validation of process
 - QC-61-06 Outdated product distributed
- QC-62-** Shipping and storage
 - QC-62-01 Other
 - QC-62-02 Product shipped at incorrect temperature
 - QC-62-03 Product stored at incorrect temperature
- QC-63-** Product identified as unacceptable, and not quarantined
 - QC-63-01 Other
- MI-**-** MISCELLANEOUS
- MI-70-** Miscellaneous
 - MI-70-01 Other